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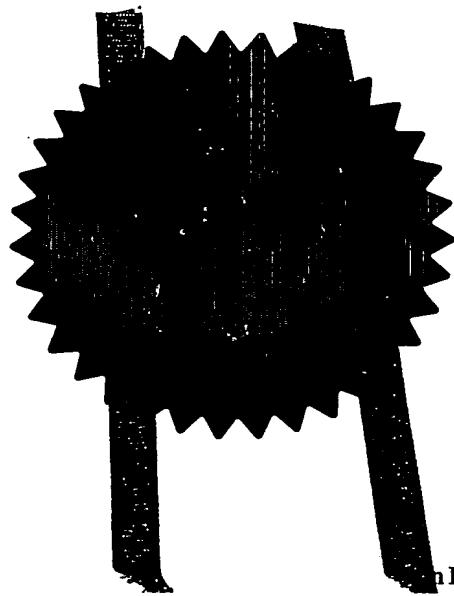
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Dated 7 October 2004

Peter Garsley

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030CT03 E841696-1 D10121
F01/7700 0-00-0323085-1**Request for grant of a patent**

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1. Your reference

P16877

2. Patent application number

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0323085.1

3. Full name, address and postcode of the or of each applicant (underline all surnames)

NORTON HEALTHCARE LIMITED,
NORTON QUAYS, ALBERT BASIN,
ROYAL DOCKS, LONDON E16 2QJ.

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

06188221005
UNITED KINGDOM

4. Title of the invention

DRY POWDER INHALATION APPARATUS

5. Name of your agent (if you have one)

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

Marks & Clerk

Clifford's Inn
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EC4A 1BZ

ADP No.-08840936001

Patents ADP number (if you know it)

08199895001

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Country

Priority application number
(if you know it)Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
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8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

- a) any applicant named in part 3 is not an inventor, or
- b) there is an inventor who is not named as an applicant, or
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See note (d))

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Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form.
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Continuation sheets of this form

Description	
Claim(s)	13
Abstract	5
Drawing(s)	11+11

J. J. M.

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Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

4

Request for preliminary examination and search (Patents Form 9/77)

1

Request for substantive examination (Patents Form 10/77)

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(please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature *Edward Evans-Jones* Date
02.10.03

12. Name and daytime telephone number of person to contact in the United Kingdom

T.JOHNSON 020 7405 4916

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DRY POWDER INHALATION APPARATUS

The invention relates to dry powder inhalation apparatus namely such an apparatus for administering a dry powder medicament in a desired pre-determined dose to a user of the apparatus who typically would actuate the apparatus manually and then breathe in the predetermined dose, or, on taking a breath, would automatically actuate the device for breathing in the predetermined dose of medicament. Such breath actuation is typically used too for dispensing the desired dose of medicament into the lungs of the patient. The medicament is carried in air during inhalation so that fine particles are carried into the lungs and heavier particles are retained in the buccal cavity.

Typically such an apparatus includes a reservoir for containing the medicament in dry powdered form, the medicament in the reservoir being for a particular number of doses, 20 for example. The doses are metered from the reservoir a dose at a time on actuation by a user for removal of the powdered medicament in a desired dosage, the apparatus also including an air inlet or inlets for taking up or entraining the medicament for passage along airways through a mouthpiece of the apparatus and into the lungs of the user when he or she takes a breath.

The amounts of medicament in a particular dose are small and are typically received from the reservoir in a device having a receptacle or cup for receiving a metered dose of medicament, the device then being shifted bodily in order to transfer the metered dose to the air channels, the body of the device sealing off the discharge outlet from the reservoir during this transfer motion.

Despite the small amount of powder being dispensed, the powder making up each dose can be compacted which can mean that more than the prescribed dosage is received in the cup.

Moreover, even if there is no compaction, the medicament can be spilled from the cup on transfer and although there is a collection well for receiving spilled medicament, this also means that the required desired dosage is not administered when the user takes a breath.

Both these disadvantages of compaction and spillage generally result from the way in which the device is transferred from the discharge outlet of the reservoir to the position for passage of the medicament into the air channels.

It is accordingly an object of the invention to seek to mitigate these disadvantages of the prior art.

According to the invention there is provided dry powder inhalation apparatus, comprising a reservoir for medicament, a mouthpiece for insertion in the mouth of a user for inhalation of a predetermined dose of medicament, a delivery channel between a discharge outlet of the reservoir and the mouthpiece for delivering said predetermined dose of medicament, a device normally held adjacent the reservoir for receiving said predetermined dose of medicament from said discharge outlet and transferring it to the delivery channel, and a mechanism adapted to release the device and permit controlled movement thereof to the delivery channel for said delivery.

It will be understood that in using the invention it is possible to provide for controlled, smooth transfer of a required dose of medicament in a two-stage operation. Movement of the device is interrupted after charging with medicament for subsequent controlled movement to the position for passage of the medicament into air channel(s) forming the discharge channels.

The device may comprise a cup for receiving the said dose and a longitudinally slidable body mounting said cup, the mechanism comprising abutment means which is movable to release the device for movement to the delivery channel.

The abutment means may preferably be bodily movable by an actuation means. This provides for positive operation and actuation.

The abutment means may also comprise a resilient member which is flexible out of the path of the device. This again provides a positive operation and actuation, particularly when the resilient member may comprise a one piece member of substantially J- or U-configuration, one limb of which is movable for releasing the device.

The movable limb may have a finger-operable tab projecting from a housing apparatus, and the tab may have indicia indicating the direction of flexing of the limb for release of the device.

The actuation means may comprise a resiliently mountable slidable member which has a tab projecting through a bore of a body of the apparatus for releasing the device. This also provides for positive operation and actuation, the slidable member preferably having indicia which can be read through the bore for indicating the position of the device.

The indicia may suitably comprise a colour code indicia.

The actuation means may further comprise a resiliently and pivotably mounted detent means which is shiftable bodily about its pivot axis to release the device.

Suitably, the detent means may have a finger grippable projection which projects therefrom and through a slot in the body of the apparatus for bodily shifting of the detent when the projection is moved along the slot.

The actuating means may further comprise a resiliently mounted plunger means which has one end projecting through a bore in a body of the device and an opposite end adapted to engage the device for shifting same bodily to said delivery channel.

The plunger means may suitably have a substantially cylindrical body member connecting the one end and the opposite end, and the opposite end may be enlarged relative to the body member.

There may be a relatively soft cushion member of the opposite end for contacting the device. This provides for a cushioned, controlled motion of the device.

The actuation means may comprise an electrical, electronic or electro-mechanical means.

The actuation means may comprise a solenoid means actuated by a switch device for actuation of the device. Suitably, the switch device may be operable manually by a user, or alternatively the switch device may be operable by inhalation of a breath by a user. In either mode, a positive operation of the device can be achieved.

There may be a power source for the electrical, electronic or electro-mechanical means.

There may be a cover for an end of the discharge channel at the mouthpiece, and the cover may be movable between a position covering the discharge channel and a position for discharging said dose, whereby to allow actuation of the mechanism.

The cover may suitably comprise a relatively rigid disc carried by opposed arms which at an end thereof opposite the disc mount a cam which has a profile for allowing movement of a cam follower in a direction away from the device whereby to allow operation of the actuation means for bodily movement of the abutment means.

The disc in its first mentioned position may be housed within a guard of the apparatus, which guard is pivotably mounted for access to the disc.

There may be a yoke member which is shiftable bodily towards and away from the mouthpiece and mounting limbs, one of which has a cam follower for following a cam which is rotatable for actuation of the yoke member which carries the actuation means in the form of a ramp up which a part at least of the device can travel for controlled movement thereof towards the delivery channel. This again provides a positive operation, particularly when the actuation means comprises a return element for returning the device to the charging position.

Such a return element may suitably comprise an inclined ledge down which the part travels to said discharge outlet.

The apparatus may be a breath actuatable apparatus.

The mechanism may be between opposed spaced walls of the reservoir and may have a member which may be retractable on a user taking a breath on the mouthpiece.

The mechanism may comprise cooperating rotatable means one of which has a detent for engaging the device and the other of which is operable to maintain the detent in engagement with the device and to allow rotation of the one means to release the detent and device.

The mechanism may further comprise a stop member, retractable as a user taking a breath on the mouthpiece, and adapted to release the other rotatable means and the detent.

The rotatable means may comprise cam or gear means.

The stop member may suitably comprise an elongate mounted member which is biased to engage the other rotatable means and a flap valve which is operable to allow air into a space between said opposed walls to equalise air pressure inside and outside the space and bias the elongate members to operate the cam or gear means.

The device may be mounted under pressure resilient means, suitably spring means.

There may also be damper means for damping movement of the device.

Embodiments of the apparatus according to the invention are hereinafter described, by way of example, with reference to the accompanying drawings.

Fig. 1 shows a perspective view of a typical dry powder inhalation apparatus;

Fig. 2 shows an exploded perspective view of a typical dry powder inhalation apparatus like that of Fig. 1;

Fig. 3 shows to a much enlarged scale a perspective view of an embodiment of device for dispensing a desired dose of medicament according to the invention;

Fig. 4 shows to a much enlarged scale a perspective view of a second embodiment of device for dispensing a desired dose of medicament according to the invention;

Figs. 5A and 5B shows respectively two operative positions of a third embodiment of apparatus according to the invention;

Fig. 6 shows a plan view of a fourth embodiment of apparatus according to the invention;

Fig. 7 shows schematically a fifth embodiment of apparatus according to the invention;

Fig. 8 shows schematically a perspective view of a further embodiment of apparatus according to the invention;

Fig. 9 shows schematically a further embodiment of inhalation device according to the invention;

Fig. 10 shows in (a) – (d) different positions of yet further apparatus embodying the invention;

Fig. 11 shows part of actuating mechanism of the embodiment of Fig. 10;

Fig. 12 shows schematically a breath operated dry powder inhalation device;

Fig. 13 shows part of the device of Fig. 12 shown in an embodiment according to the invention; and

Fig. 14 shows a way of mounting the device of the apparatus of the previously described embodiment.

Referring to the drawings (see for example Figs. 1, 2, 9), and in which like parts are referred to by like numerals where feasible, there is shown dry powder inhalation apparatus 1, comprising a reservoir 2 for medicament, a mouthpiece 3' for insertion in the mouth of a user for inhalation of a predetermined dose of a medicament, a delivery channel 3 between a discharge outlet 4' of the reservoir 2 and the mouthpiece for delivering said predetermined dose of medicament, a device 4 normally held adjacent the reservoir for receiving a predetermined dose of medicament from said discharge outlet and transferring it to the delivery channel, and a mechanism 5 adapted to release the device 4 and permit controlled movement thereof to the delivery channel for said delivery.

Fig. 1 shows the general outline of the inhalation apparatus 1 from in front there being a pivotable cover 6 at the bottom (and as used) of a body 7 of the device.

As shown in Fig. 2, the housing or body 7 of the apparatus 1 includes a cap 8, an internal spring 9, a yoke 10, a bellows 11, an actuating mechanism including a further yoke 12, a counter 13, viewable in the base 14 of the body 7 mounting the mouthpiece cover 6.

The mechanism 5 (Fig. 3 for example) includes the device 4 which is generally movable transversely of a longitudinal axis of the apparatus 1 for receiving in a cup or receptacle 15 a metered dose of powdered medicament which is then transferred by the shifting of the device 4 to the discharge channels or airways 3 which when a patient breathes in on sucking on the mouthpiece 3', removes the powdered metered dose from the cup or receptacle 15 so that it is entrained in the air and passes through the mouthpiece 3' into the lungs and mouth of the user. Charging of the cup or receptacle 15 with medicament is effected from a discharge outlet 4' of the reservoir 2 by the bellows 11 on movement of the yoke 10 in a position towards the mouthpiece 3', there being a part in the form of a shoulder, boss or abutment 16 of the device 4, for shifting the device longitudinally bodily from the discharge outlet 4' to the air delivery channel 3.

In order to provide a smooth operation, there is positioned at the fore end of the device 4 an abutment 5 which has physically to be moved bodily out of the way of the device and, as shown in Fig. 3, this abutment is of L-shape which on movement by finger pressure on an end 17 shifts the abutment 5 so that an upstanding integral part 18 thereof is clear of the adjacent end of the device 4 so that the device 4 can then be moved smoothly to the discharge position under pressure of a spring (which is not shown).

Fig. 4 shows a further embodiment in which the abutment comprises a resilient member 19 in the form of in the embodiment shown a J-shaped plastic spring-like member, the lower

or shorter limb 20 of which is secured in the body 7 of the apparatus 1 and the upper limb 21 of which is able to be flexed out of the path of the device 4 on movement of a tab 22 downwardly as shown by the indicia 'A' in the form of an arrow on the outside surface thereof.

When the underside of the longer limb 21 meets the upper surface of the lower limb 20 and therefore cannot be lowered further, the user knows that when it is positive "stop" the desired medicament is available for inhalation.

Turning now to Figs. 5A and 5B, the mechanism 5 includes a pivotable stop 23. The stop 23 is of generally L-shape and is mounted for pivotable movement on an axis 24 under spring pressure 25 which tends to bias it towards a position obstructing movement of the device 4.

The pivot 24 is mounted in holes 26 in facing members of upper and lower flanges 27, 28 of the reservoir or hopper 2.

There is a projection 29 from one limb of the abutment member 23, the projection 29 being accessible manually through an orifice 30 in a wall of the body 7 by a user who on turning the projection 29 in the direction shown by the arrow 31, releases the device 4 for smooth but positive motion to the discharge position, the projection 29 when it meets a blind wall of the orifice 30 effectively informing the user that the desired dosage of medicament is again available for inhalation.

Fig. 6 shows a yet further embodiment in which there is a slidable ring member 32 which is mounted under pressure of a spring 33 to be biased to a position in which a projection 34 of the ring 32 interferes with the motion of the device 4. The ring member 32 also includes a button 35 which projects through an opening or orifice 36 in a wall 7 of a body of the apparatus 1.

The ring 32 includes indicia 37 either in lettering or in colour, for example in red and green showing when the device 4 is not ready for dispensation (red) or is ready for dispensation and thus inhalation (green).

The user can read this indicia when the button is pushed from left to right as shown by the arrow 'X' in Fig. 6, thereby releasing the device 4 and thus make the medicament ready for inhalation.

Turning now to Fig. 7, an embodiment is shown in which a button or plunger 38 mounted in a wall 7 of the apparatus 1 under spring 39 pressure is biased away from contact with an abutment of the device 4, but on actuation of a head 40 of the plunger inwardly the opposite end 41 thereof which is enlarged relative to a cylindrical body 42 of the plunger contacts the device 4 and shifts it bodily and smoothly to the left as viewed ready for discharge to the air channels, on inhalation.

Release of the button 38 retracts the plunger so that the device 4 itself can return for further charging, the device as in all embodiments, being mounted under spring pressure which biases it towards the charging position. The enlarged opposite end 41 of the plunger 38 may include a cushion (not shown) for providing a cushioned contact of the plunger with the device 4.

Fig. 8 shows a yet further embodiment in which there is an actuator 43 such as an electrical, electronic or electro-mechanical actuator having an extensible actuating member such as a piston rod 44 which on operation of the actuator 43 extends to push the abutment 45 of the mechanism out of the path of the device 4, for discharge as before. The actuator 43 in this embodiment includes a switch 46, and a power source 47 such as a battery. The switch 46 may be operated manually, or automatically when a user takes a breath.

Turning now to Fig. 9, there is shown an embodiment in which the mouthpiece 3' is normally covered by a flap or disc 48 which is mounted on two arms 49 at the end of which opposite the flap or disc 48 there is a cam device 50 which operates the operating mechanism by allowing a cam 51 to follow the shape of the cam 50 thereby to allow the cup of the device to be charged and then for a mechanism like that labelled (5) in Fig. 3 but not shown in Fig. 9, to allow for smooth transfer of the device 4 for discharge of the inhalation dose with the medicament as described hereinbefore.

The flap, or cover 48, carries externally an indicia 52 such as an arrow to indicate to a user the direction in which the flap should be pivoted to effect operation and to expose the mouthpiece 3' for inhalation, the cover in the closed position of the mouthpiece being itself closed by a pivotable external cover 6.

Turning now to Figs. 10 and 11, there is shown schematically a mechanism in which the part 16 of the device 4 is initially in the rest position shown in (a) against a ratchet part of a yoke 12 which has a lower cam 53 and which is resilient and profiled in a direction orthogonal to that as viewed, as by being convex. When that yoke 12 is actuated and pulled down for charging the cup 15 with the desired dosage of medicament, the part 16 rides up the ratchet as shown at (b) and then, to effect transfer, it moves gently and smoothly upwardly along a ramp 54 owing to the resilience and profile of the ratchet as shown at (c). On return of the ratchet upwardly, arrow 'Y', the part 16 of the device 4 is engaged by a downward sloping element 55 (left to right as viewed in (b)), and, in order to accommodate upward movement of the ratchet, the part 16 of the device 4 moves down the slope or return element 55 thereby returning the device 4 to the position for charging.

This action is exemplified in Fig. 11 where the lower end of the yoke 12, adjacent the mouthpiece, follows a single cam follower 56 of a cam which is rotatable by the mouthpiece, or cover (Fig. 9).

Fig. 12 shows a breath actuated dry powder inhalation apparatus 57 in which there is a force handling unit 58 on top of a lower body part 59 of the apparatus 57, the device 4 being actuatable only when the patient takes a breath as known from previous breath operated examples such as that marketed under the trade mark Easi-Breathe. In this embodiment when the patient inhales a mechanism 60 shown in Fig. 13 is operative to provide for dispensation of the required dose of medicament. In this embodiment, between the upper 61 and lower 62 flanges of the reservoir 2, there is a two cam or gear arrangement, the first or upper 63 one of which as viewed has an extension 64 which engages the device 4 to hold it in the charging position, there being an elongate actuating member 65 which is operative to rotate the cam or gear 67 whereby it in turn can rotate the cam or gear 63 out of contact with the device 4 thereby allowing the device 4 to move for inhalation.

The elongate member 65 is mounted under pressure of a spring 66 there being a valve and seal arrangement 68 operable when a patient breathes on the mouthpiece to lift a flap valve 69 thereof, thereby allowing atmospheric air to enter a space 70 defined between the upper and lower flanges 61, 62 of the reservoir and between a wall 71 spacing those two flanges apart so that the spring 66, under the pressure of which the elongate member is mounted, is retracted thereby, the air pressure either side of the wall being equalised.

Turning now to Fig. 14, this shows schematically the device 4 mounted underneath the charging opening 4' from the reservoir 2 so that the cup 15 is aligned with that charging opening. The device 4 is mounted under pressure of a spring to return to the position shown, there is also a damper device 72 such as a dash pot which on operation of the mechanism to move the device longitudinally bodily to the left as shown by the arrow 'R', is active to provide a smooth, controlled passage from the charging opening to the air channel, for inhalation of the desired predetermined dose of powdered medicament.

All the embodiments herein described with reference to the accompanying drawings describe dry powder inhalation apparatus which provides for charging of a cup of a discharge device without compaction and for smooth and controlled transfer of the device to air channels thereby avoiding compaction, and spillage, so that on repeated operation, the desired metered dose will be dispensed each time a patient uses the apparatus.

CLAIMS

1. Dry powder inhalation apparatus, comprising a reservoir for medicament, a mouthpiece for insertion in the mouth of a user for inhalation of a predetermined dose of medicament, a delivery channel between a discharge outlet of the reservoir and the mouthpiece for delivering said predetermined dose of medicament, a device normally held adjacent the reservoir for receiving said predetermined dose of medicament from said discharge outlet and transferring it to the delivery channel, and a mechanism adapted to release the device and permit controlled movement thereof to the delivery channel for said delivery.
2. Apparatus according to Claim 1, the device comprising a cup for receiving the said dose and a longitudinally slidable body mounting said cup, the mechanism comprising abutment means which is movable to release the device for movement to the delivery channel.
3. Apparatus according to Claim 2, the abutment means being bodily movable by an actuation means.
4. Apparatus according to Claim 2, the abutment means comprising a resilient member which is flexible out of the path of the device.
5. Apparatus according to Claim 4, the resilient member comprising a one piece member of substantially J- or U-configuration one limb of which is movable for releasing the device.

6. Apparatus according to Claim 5, the movable limb having a finger-operable tab projecting from a housing of the apparatus.
7. Apparatus according to Claim 6, the tab having indicia indicating the direction of flexing of the limb for release of the device.
8. Apparatus according to Claim 3, the actuation means comprising a resiliently mountable slidable member which has a tab projecting through a bore of a body of the apparatus for releasing the device.
9. Apparatus according to Claim 8, the slidable member having indicia which can be read through the bore for indicating the position of the device.
10. Apparatus according to Claim 9, the indicia comprising a colour code indicia.
11. Apparatus according to Claim 3, the actuation means comprising a resiliently and pivotably mounted detent means which is shiftable bodily about its pivot axis to release the device.
12. Apparatus according to Claim 11, the detent means having a finger grippable projection which projects therefrom and through a slot in the body of the apparatus for bodily shifting of the detent when the projection is moved along the slot.
13. Apparatus according to Claim 3, the actuating means comprising a resiliently mounted plunger means which has one end projecting through a bore in a body of the device and an opposite end adapted to engage the device for shifting same bodily to said delivery channel.

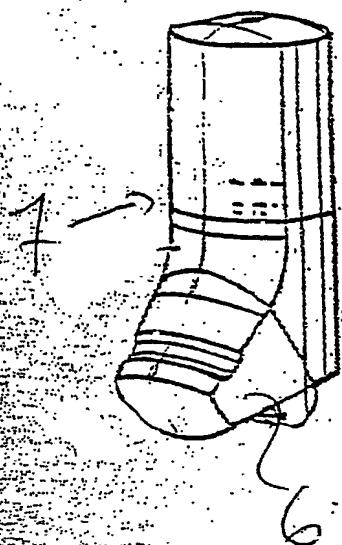
14. Apparatus according to Claim 13, the plunger means having a substantially cylindrical body member connecting the one end and the opposite end, the opposite end being enlarged relative to the body member.
15. Apparatus according to Claim 14, there being a relatively soft cushion member of the opposite end for contacting the device.
16. Apparatus according to Claim 3, the actuation means comprising an electrical, electronic or electro-mechanical means.
17. Apparatus according to Claim 16, the actuation means comprising a solenoid means actuated by a switch device for actuation of the device.
18. Apparatus according to Claim 17, the switch device being operable manually by a user.
19. Apparatus according to Claim 17, the switch device being operable by inhalation of a breath by a user.
20. Apparatus according to any of Claims 16 to 19, comprising a power source for the electrical, electronic or electro-mechanical means.
21. Apparatus according to any preceding claim, comprising a cover for an end of the discharge channel at the mouthpiece, the cover being movable between a position covering the discharge channel and a position for discharging said dose, whereby to allow actuation of the mechanism.
22. Apparatus according to Claim 21, the cover comprising a relatively rigid disc carried by opposed arms which at an end thereof opposite the disc mount a cam which has a profile for allowing movement of a cam follower in a direction

away from the device whereby to allow operation of the actuation means for bodily movement of the abutment means.

- 23. Apparatus according to Claim 22, the disc in its first mentioned position being housed within a guard of the apparatus, which guard is pivotably mounted for access to the disc.
- 24. Apparatus according to Claim 3, comprising a yoke member which is shiftable bodily towards and away from the mouthpiece, and mounting limbs one of which has a cam follower for following a cam which is rotatable for actuation of the yoke member which carries the actuation means in the form of a ramp up which a part at least of the device can travel for controlled movement thereof towards the delivery channel.
- 25. Apparatus according to Claim 24, the actuation means comprising an element for returning the device to the discharge outlet.
- 26. Apparatus according to Claim 25, the element comprising an inclined ledge down which the part travels to said charging position.
- 27. Apparatus according to Claim 3, comprising a breath actuatable apparatus.
- 28. Apparatus according to Claim 27, the mechanism being between opposed spaced walls of the reservoir and having a member which is retractable on a user taking a breath on the mouthpiece.
- 29. Apparatus according to Claim 28 the mechanism comprising cooperating rotatable means one of which has a detent for engaging the device and the other of which is operable to maintain the detent in engagement with the device and to allow rotation of the one means to release the detent and device.

30. Apparatus according to Claim 29, the mechanism further comprising a stop member retractable as a user takes a breath on the mouthpiece, and adapted to release the other rotatable means and the detent.
31. Apparatus according to Claim 30, the rotatable means comprising cam or gear means.
32. Apparatus according to Claim 30 or 31, the stop member comprising an elongate mounted member which is biased to engage the other rotatable means and a flap valve which is operable to allow air into a space between said opposed walls to equalise air pressure inside and outside the space and bias the elongate member to operate the cam or gear means.
33. Apparatus according to any preceding claim, the device being mounted under pressure resilient means.
34. Apparatus according to Claim 33, the resilient means comprising spring means.
35. Apparatus according to any preceding claim, there being damper means for damping movement of the device.

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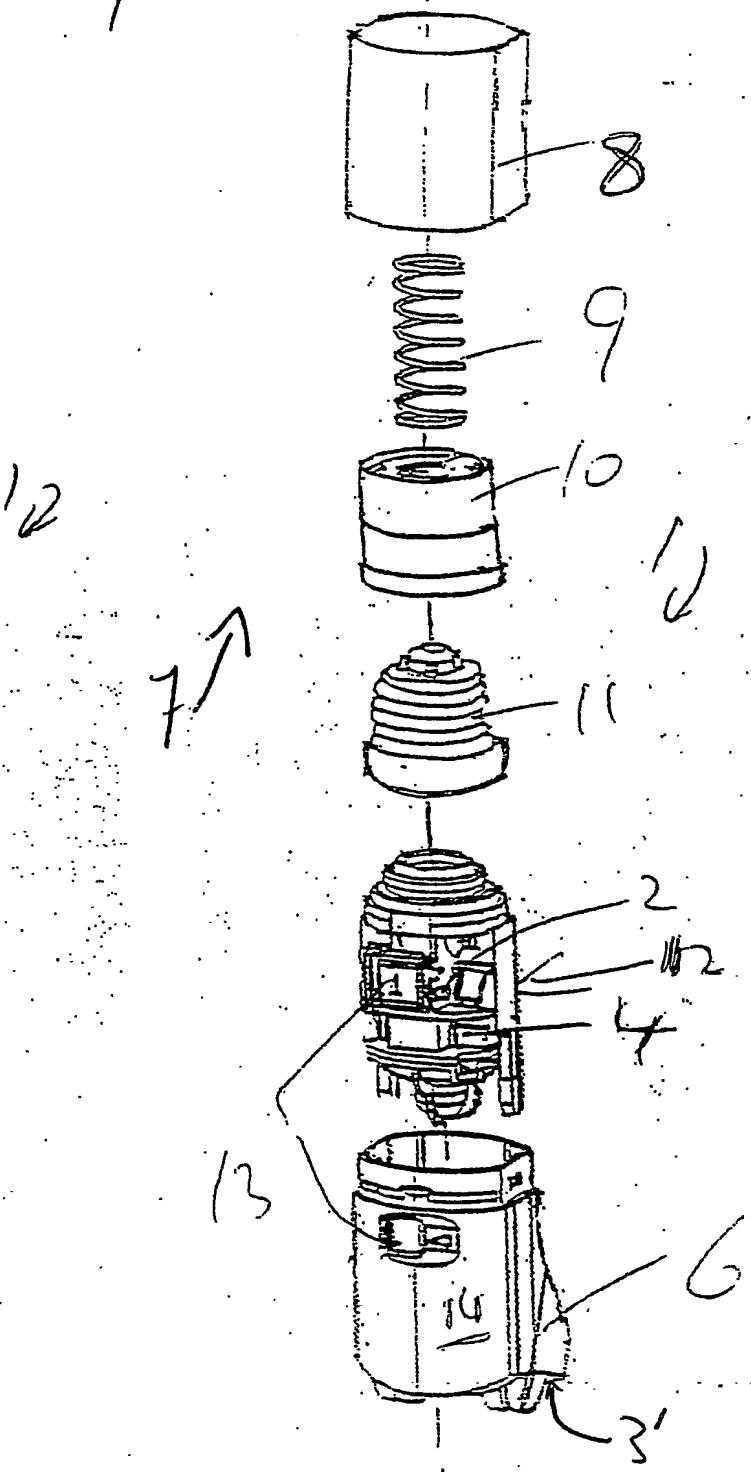
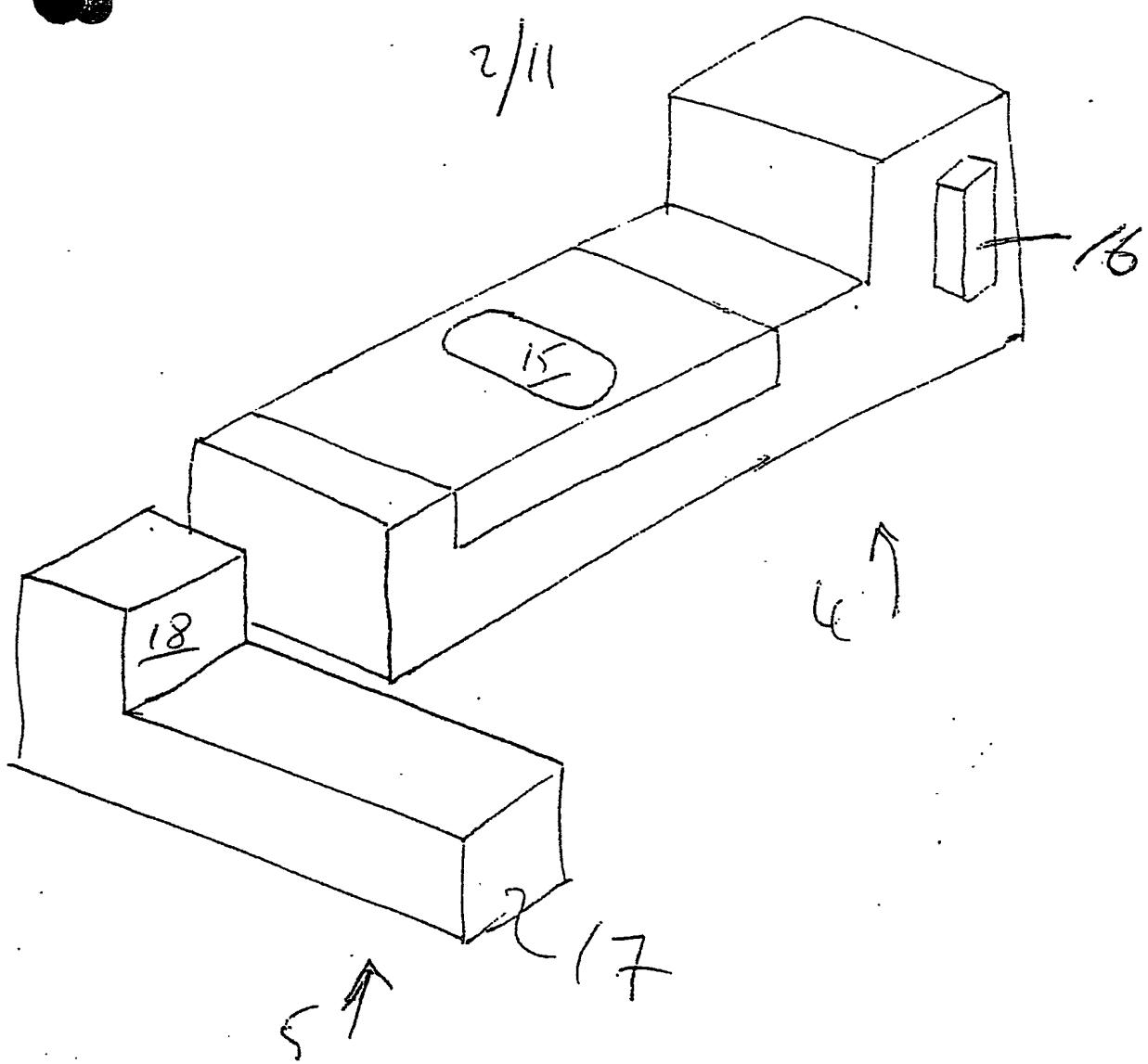


FIG 2



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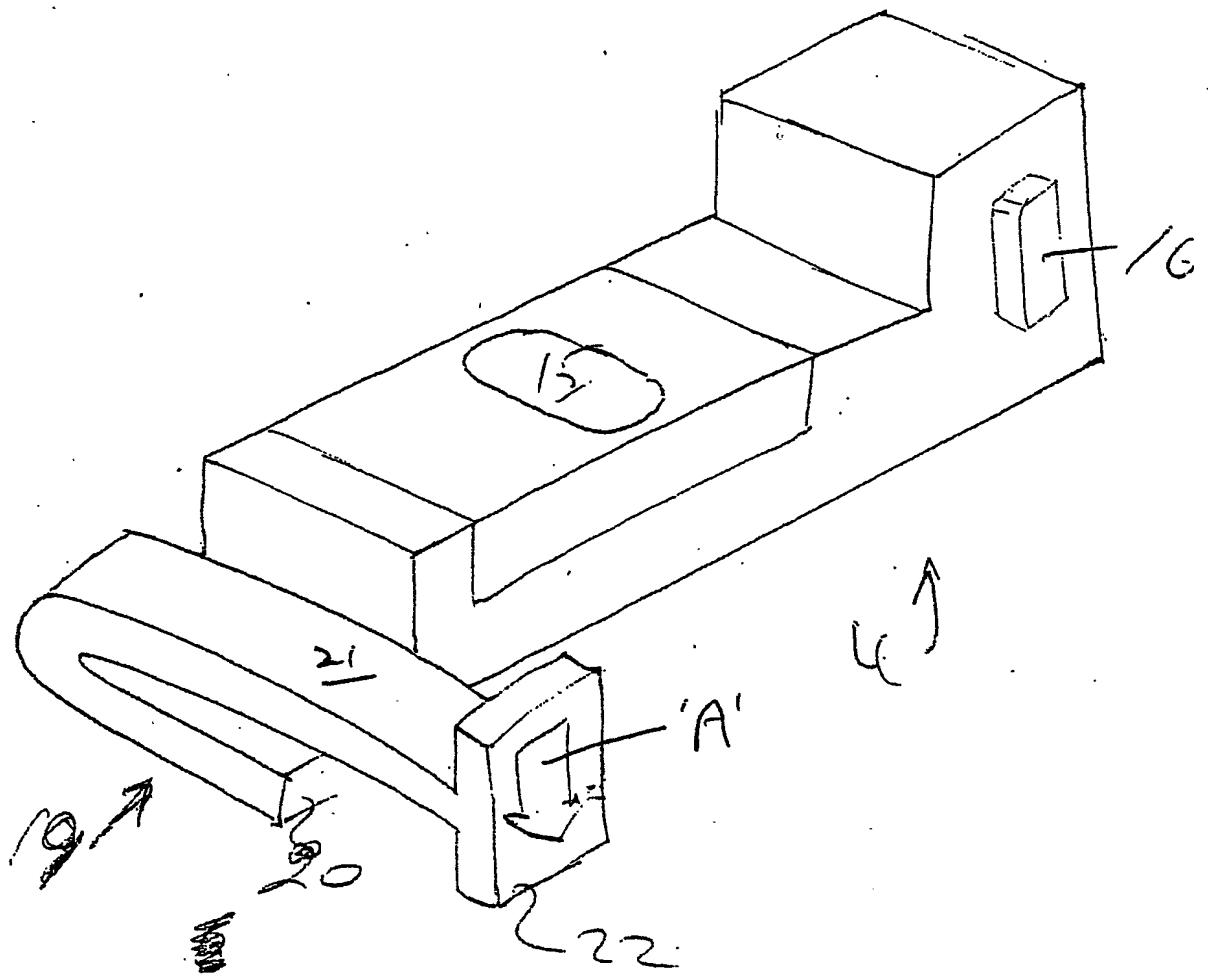


Fig 4

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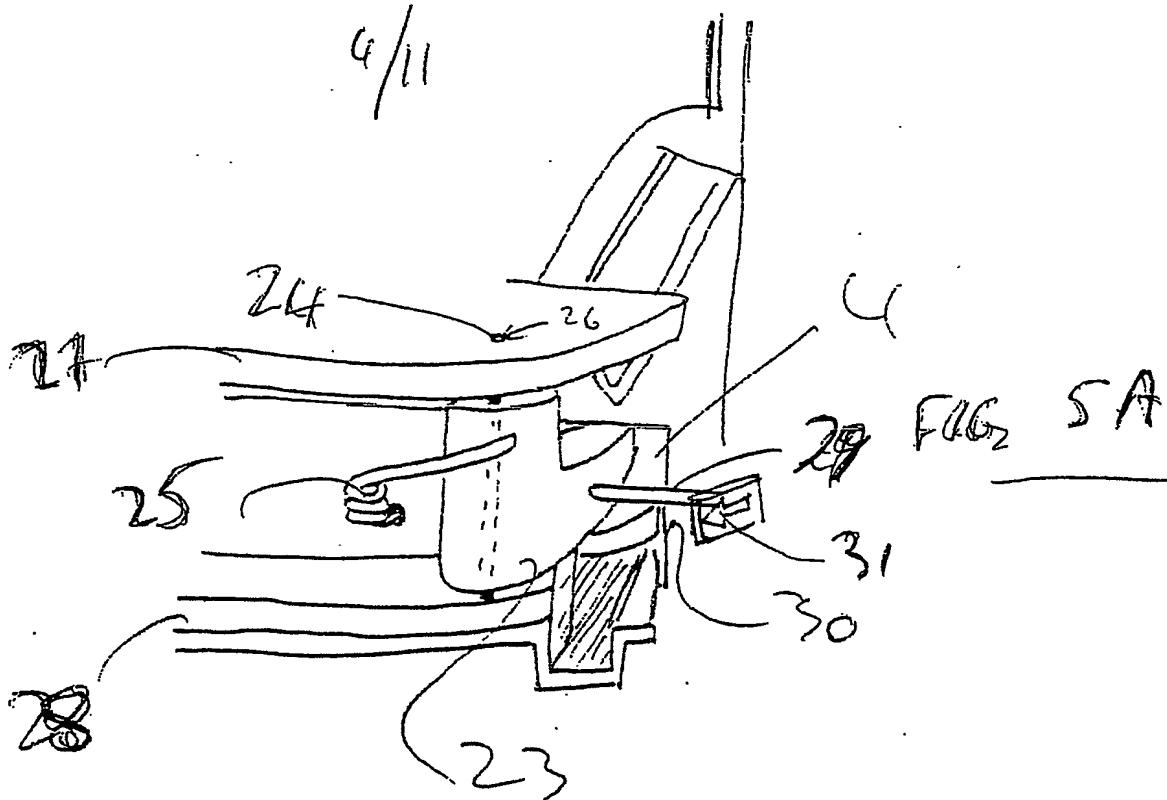


FIG 5A

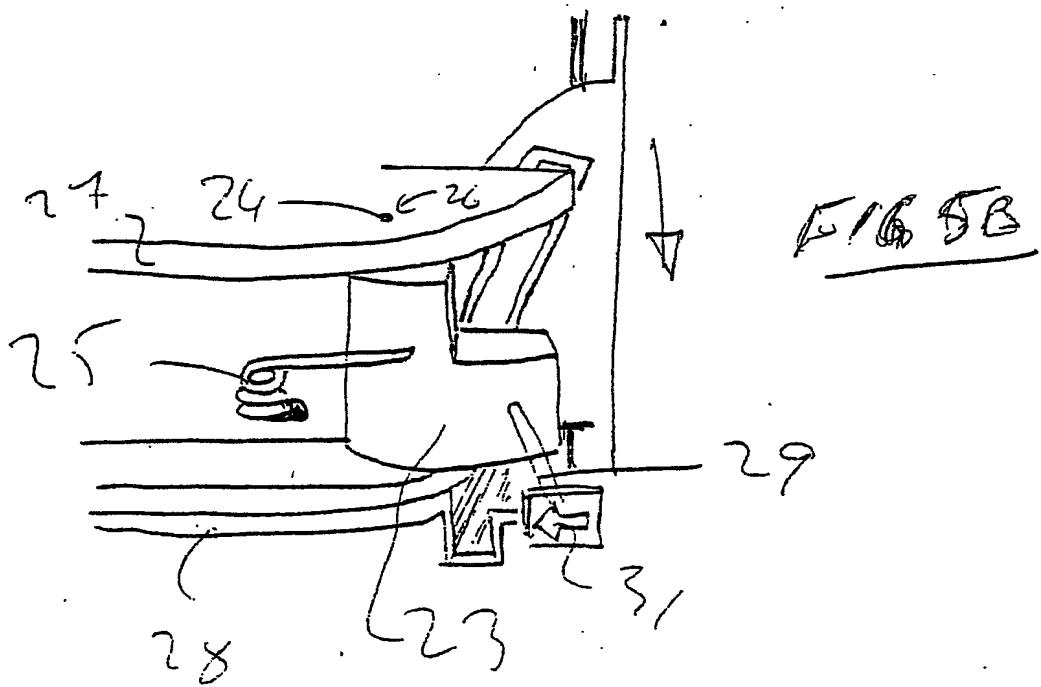
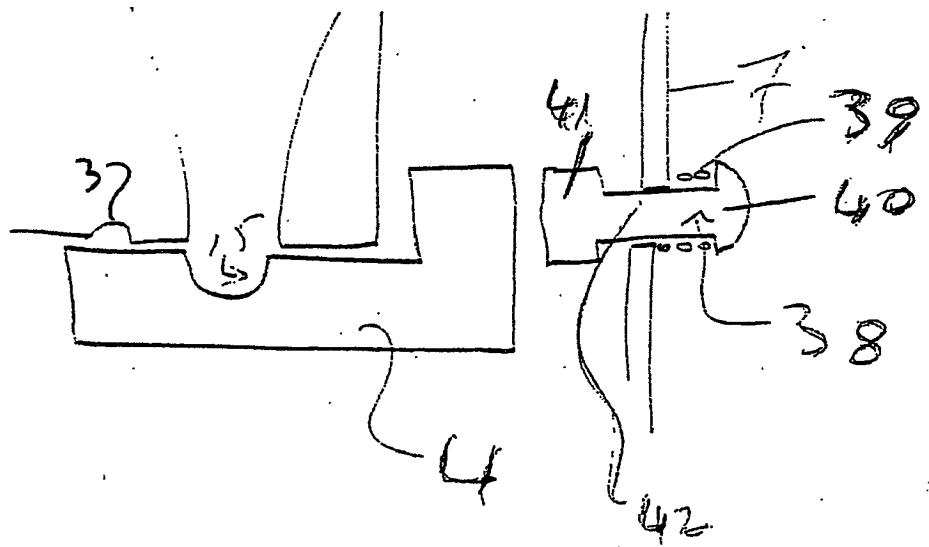
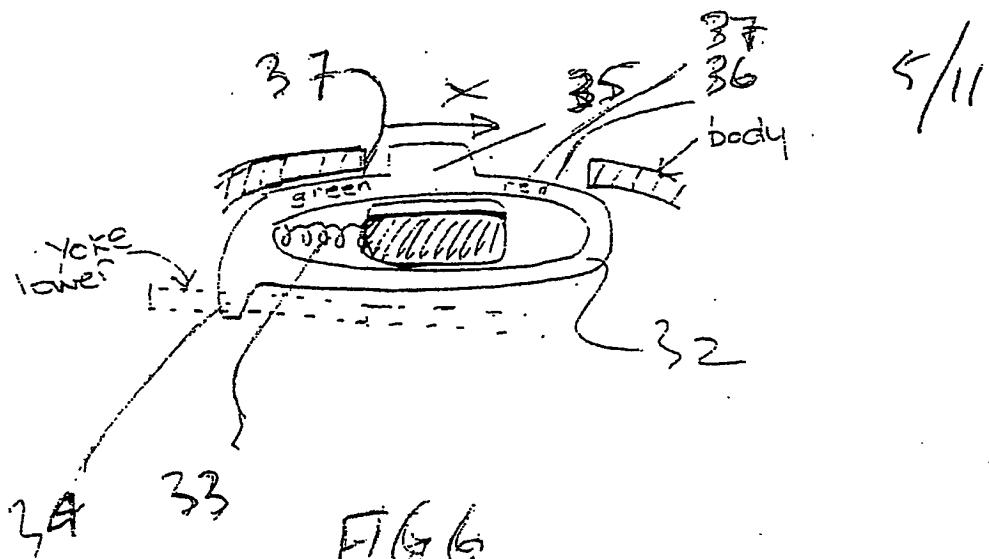


FIG 5B



三(4)7

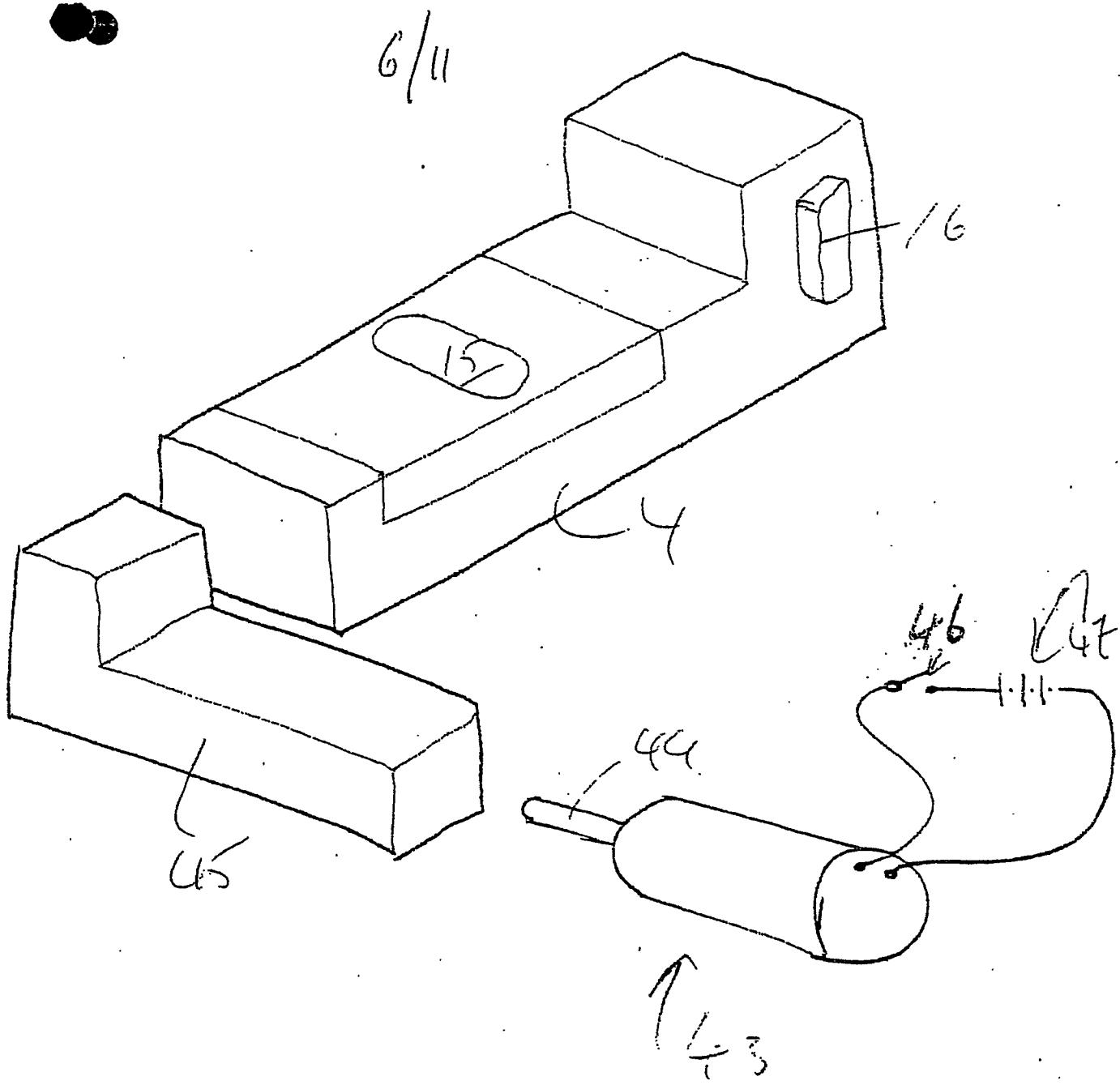
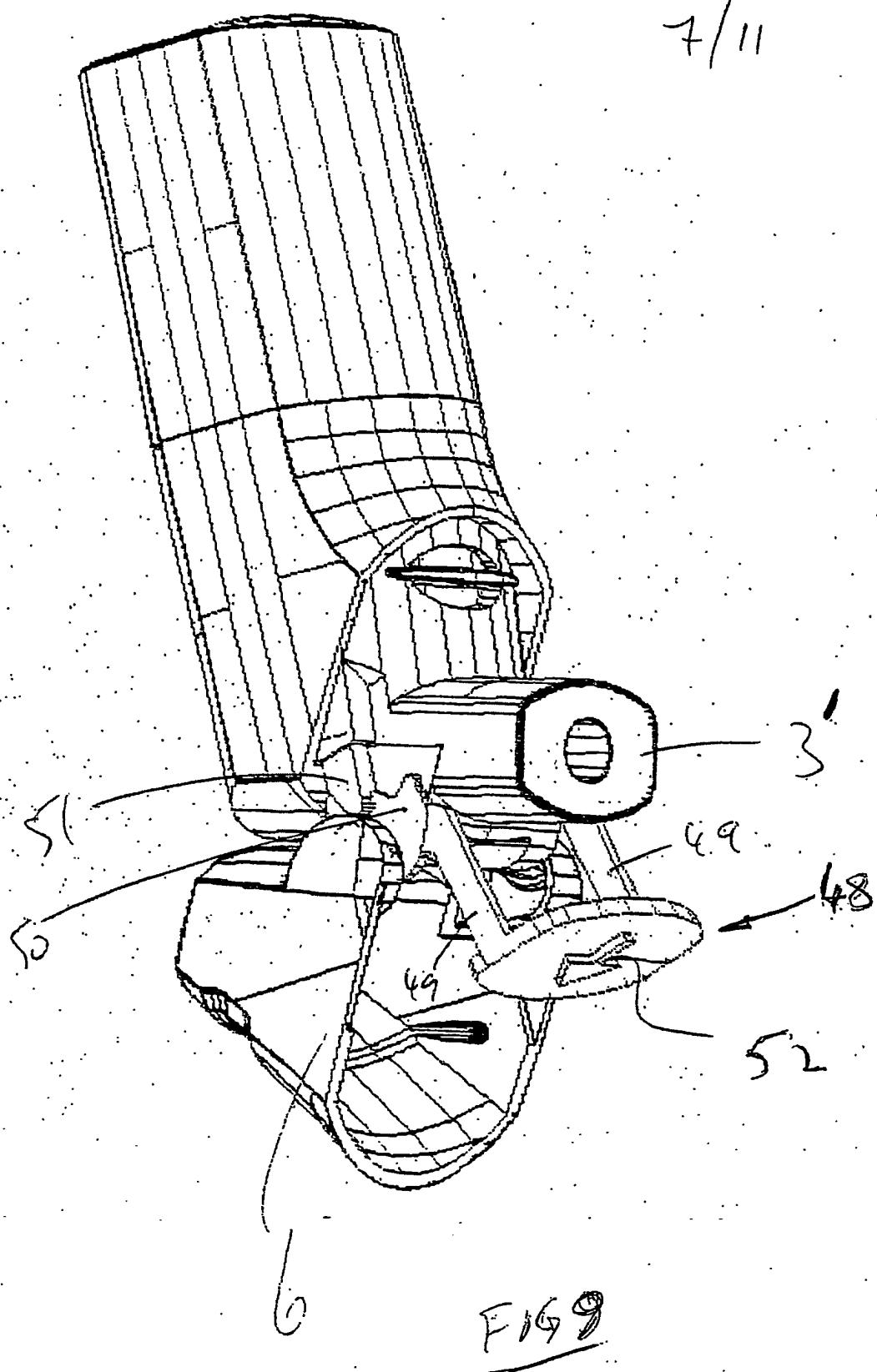


FIG 8

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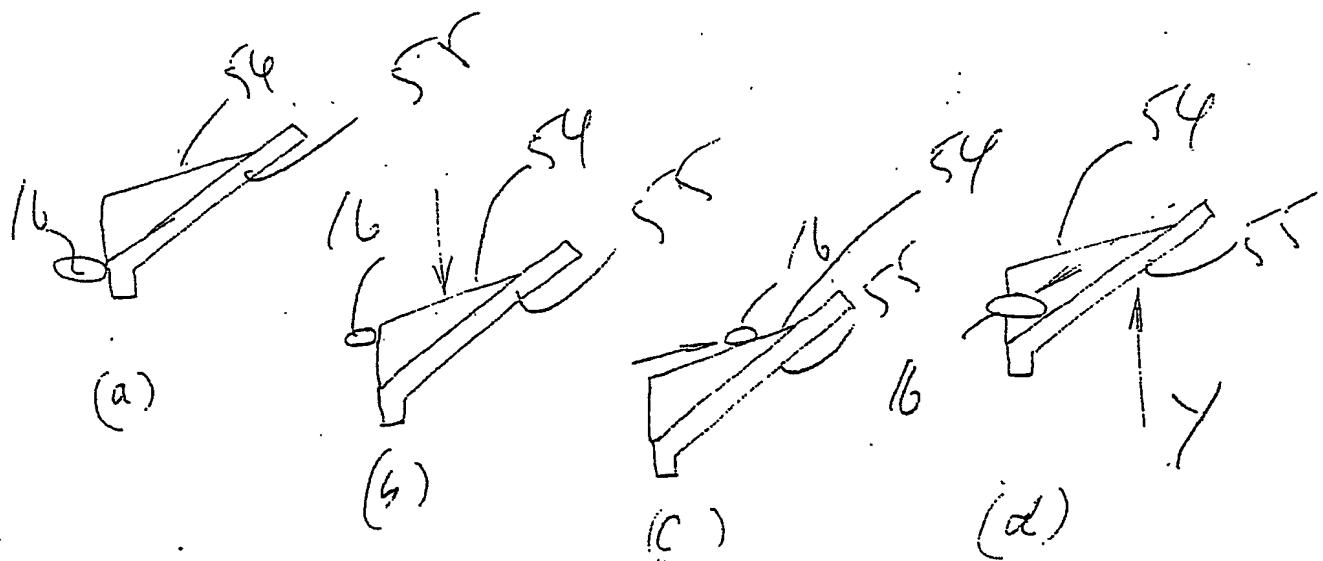


FIG 10

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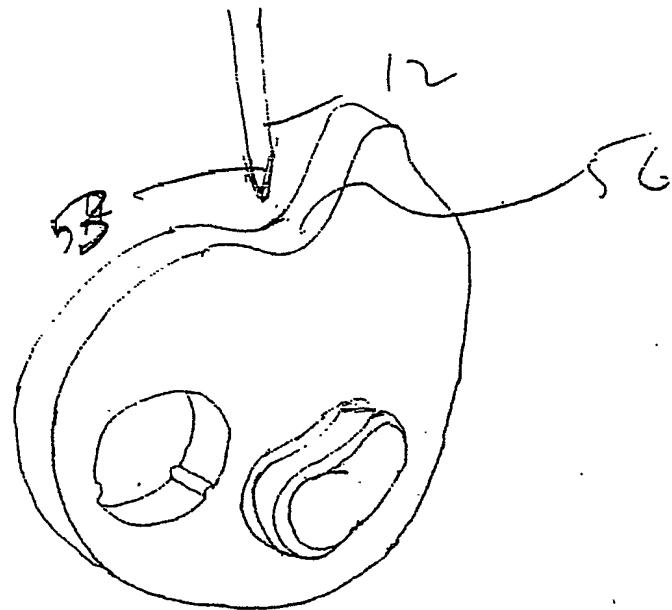
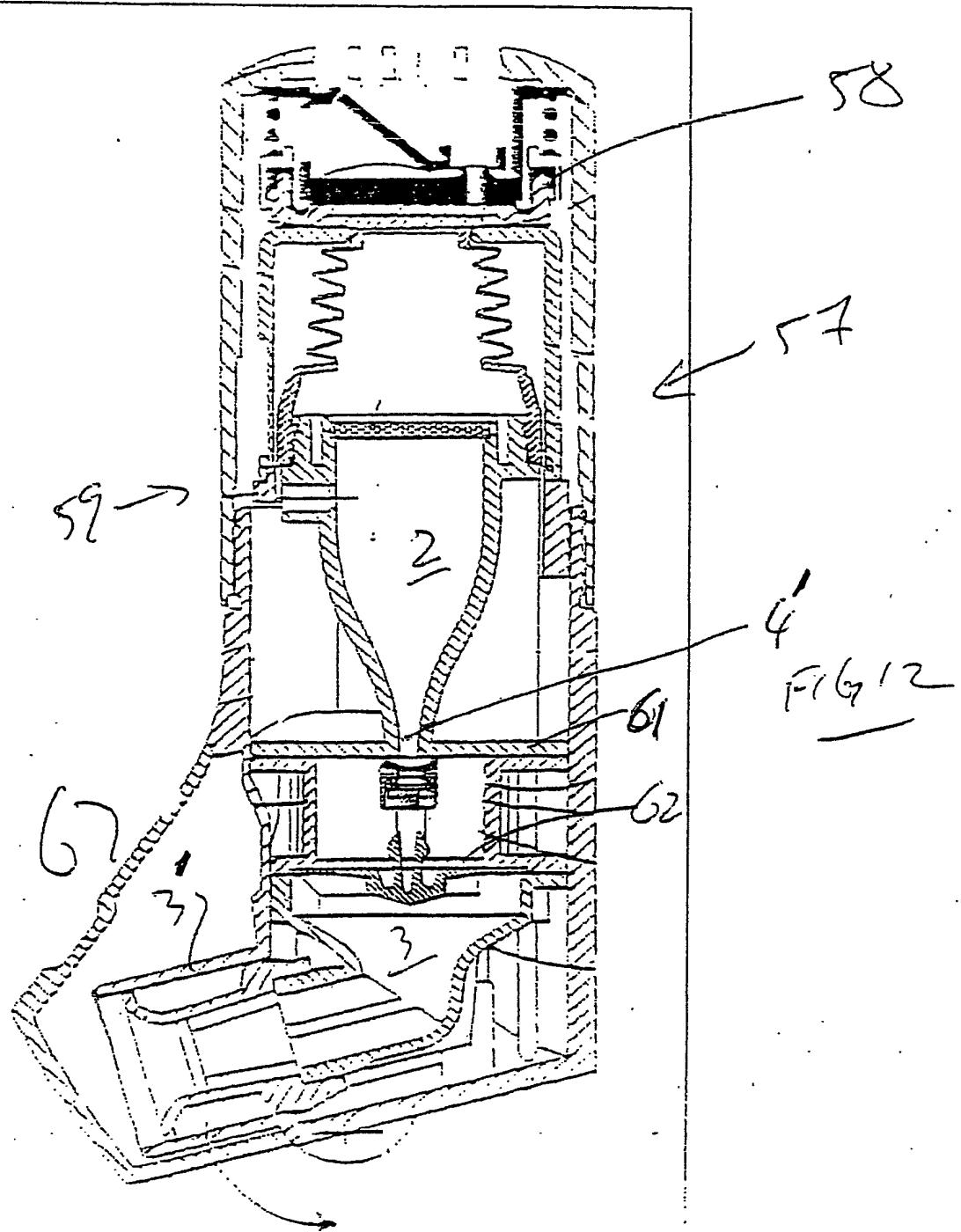


FIG 11

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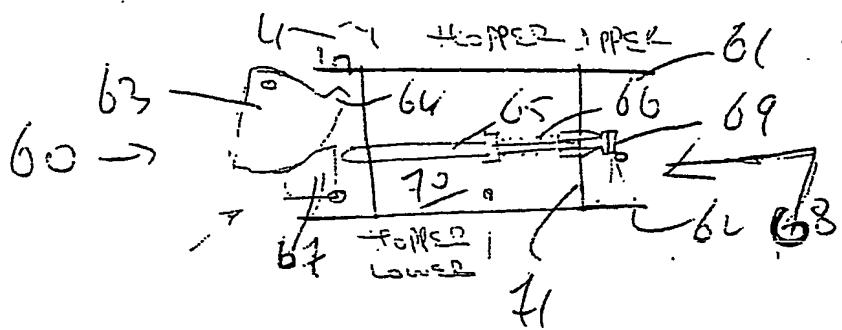


Fig. 13

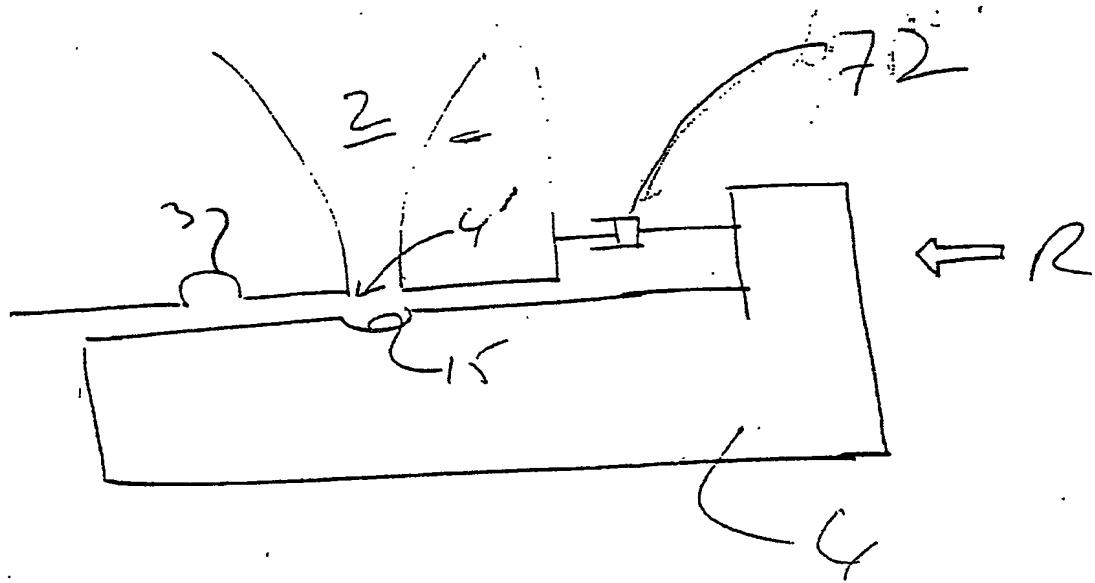


Fig. 14

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